

Auriculotherapy for Chronic Cervical Pain: A Prospective Observational Study

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ABSTRACT

Objective: Chronic cervical pain is a common and recurrent complaint. Auriculotherapy (AT) or ear acupuncture is an effective complementary method used for pain control, but only a few studies have evaluated this treatment for chronic cervical pain. Thus, the aim of this study was to analyze the effectiveness of AT to control chronic cervical pain and improve functional capacity.

Materials and Methods: This prospective observational study involved patients with at least 2 years of cervical pain and a neck disability index score (NDI) >5. AT was performed at detectable points once per week over 6 weeks. Patients were evaluated with the NDI and a visual analogue scale (VAS) for pain before and at 1 and 4 months after the final treatments. An analysis of variance test for repeated measures was used for comparisons.

Results: During the study, 19 patients, with a mean ($\pm$ SD) age of 44.5 ± 15.2 years, were enrolled. The majority of the patients were right-handed (89%) and female (79%). The median (interquartile range) disease duration was 48 months (range: 24–66 months). An average of 4 ear points were used per session; the most frequent points used were: *Shen men*, Posterior Wall, Zero, and C1. Statistically significant decreases in NDI (15.58 ± 5.93) and VAS (4.76 ± 2.37) scores were observed at 1 and 4 months (8.84 ± 5.59 ; $P < 0.0001$ and 3.21 ± 2.12 ; $P = 0.003$, respectively) after AT treatment.

Conclusions: AT can be used successfully as a complementary method to treat chronic cervical pain.

Keywords: auriculotherapy, cervical pain, neck pain, auricular acupuncture

INTRODUCTION

AURICULOTHERAPY (AT) OR EAR ACUPUNCTURE is a therapeutic technique in which specific ear points are stimulated by needles.¹ In 1990, AT was recognized by the World Health Organization as an acupuncture microsystem with 43 auricular points.¹ The therapy is based on the principle that, when disharmony occurs in any part of the body, this disharmony is reflected in the ear with reactions of specific characters and localities, related to particular diseases. This is supported by fundamentals of neurophysiology that were re-

cently confirmed in studies using functional magnetic resonance imaging.^{2–4} The technique uses painful palpation with a calibrated pressure probe (250 g/mm^2) and a differential electrical detector to diagnose the point(s) to be treated.³

Spinal pain is the most common type of chronic pain, mostly located at the low-back region and followed by the cervical area.^{1,5} The main indication for AT is pain treatment, whether the pain is acute or chronic. As cervical pain is expected to occur in between 30% and 50% of the general population every year,⁶ it is surprising that only a couple of studies have investigated AT for treatment of cervical

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pain.^{7,8} Thus, the primary objective of this study was to investigate the effectiveness of AT—applied by the French technique—for pain control and improving functional capacity in patients with cervical pain.

MATERIALS AND METHODS

This study was performed at the Fundação Técnico-Educacional Souza Marques and the Universidade Federal do Rio de Janeiro, Campus Macaé, both in Rio de Janeiro, Brazil.

Participants

In this prospective observational study, patients were recruited from an outpatient clinic in Cabo Frio, Brazil, between July and August 2020. The study was registered in the Brazilian Registry of Clinical Trials (ReBEC; No. RBR-3rkv2pf) and approved by the research ethics board of Universidade Federal do Rio de Janeiro (No. 4.141.082). Informed consent for participation in the study was obtained from all patients.

Adult patients over 18 years old with at least 2 years of cervical pain as the main complaint and a neck disability index (NDI) score >5 were eligible. Patients with histories of surgery, fractures, or severe injuries in the cervical region; allergies or injuries in both ears; serious systemic pathologies, such as autoimmune diseases and cancer; and

pregnancy were excluded. For study entry, all patients had to accept not to receive other treatments during the study timeperiod, except for analgesics, if necessary.

Auriculotherapy Treatment and Study Design

Auriculotherapy treatment protocols were adapted according to each patient. Nogier's cartography of the ear was applied⁵ and previously described recommendations¹ were followed to survey the points and zones: C1; Cervical Musculature in the Posterior Wall, Thalamus, Zero, *Shen Men*, and Prefrontal Cortex (Fig. 1).

Detection of ear pathologic points was performed in two ways^{1,9}: (1) painful palpation, with a probe calibrated to exert a pressure of 250 g/mm² at the point to be searched; and (2) differential electrical detection, using an EL-30 Finder electrical detector (NKL Produtos Eletrônicos, Brusque, SC, Brazil). For electrical detection, a constant pressure was applied to the coaxial bi-electrode sensor halfway, with the surface supported fully, without lateral pressure, and by performing a slow displacement on the skin. Only stable measurements of at least 2 seconds were accepted. After calibrating the device, only the points detected in low impedance were used. Then, the detected points were treated with acupuncture needles 0.25 mm × 15 mm (DONGBANG, Korea) after disinfection with 70% alcohol and left in place for 20 minutes. Six treatment sessions were carried out, 1 per week, for a total of 6 weeks.

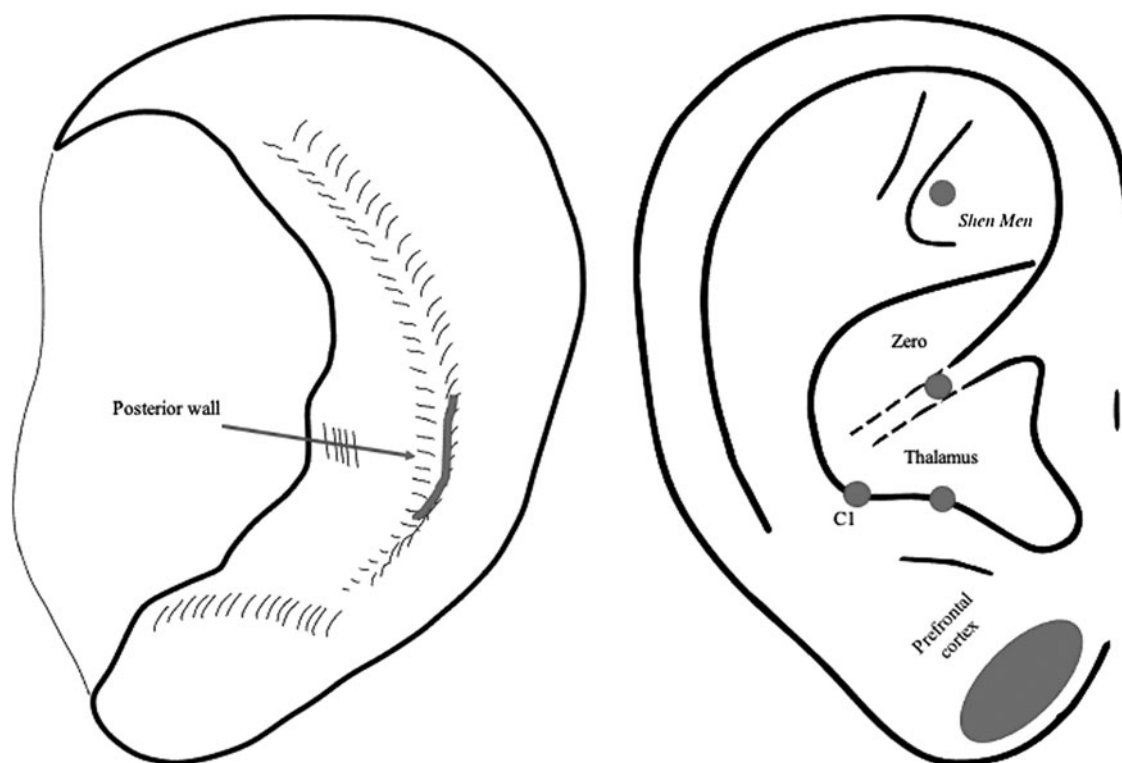


FIG. 1. Auricular points surveyed to determine auriculotherapy points to use for addressing chronic cervical pain.

Evaluation of the patients was performed before, and 1 month and 4 months after the end of treatment. The NDI questionnaire and the numerical visual analogue (VAS) for pain were applied. The NDI questionnaire was developed and validated to assess the functional capacity of the cervical region.¹⁰ It is composed of 10 questions, each of them with values from 0 to 5; higher scores indicate greater limitations. In the numerical VAS for pain, the patient indicates, in a 10-cm straight line without any markings, the degree of pain being experienced at the time of the interview. The left end of the line (0) is “no pain” and the right end (10) is “worst pain.”

Statistical Analysis and Sample Size

In the descriptive analysis, data are presented as mean $\pm$ standard deviation (SD) or median (centiles) for continuous variables, and percentages for categorical variables. All continuous variables were tested for normality using the Shapiro–Wilks test. The effects of auricular acupuncture on the scales of pain and functional capacity after 1 and 4 months of treatment were compared by using an analysis of variance test for repeated measures.

Values of $P < 0.05$ were considered statistically significant, and all tests were 2-tailed. The analyzes were performed with R Statistic, version 3.6.2 software (R Foundation for Statistical Computing, Vienna, Austria). Based on previous studies,^{11,12} the present trial was designed to detect an improvement of at least 30% in the neck NDI¹⁰ and/or in the numerical VAS of pain after 6 treatment sessions. A sample size of 13 patients would provide a 90% test power to detect this difference, with an α level of significance of 0.05. To compute possible losses from follow-up or dropouts, a sample size of 20 patients was determined.

RESULTS

A total of 20 patients were initially included in the study but 1 discontinued treatment after 2 sessions. The demographics of the remaining 19 patients (15 females and 4 males) are shown in Table 1. Before study entry, the median duration of cervical pain was 48 months (interquartile range: 24–66 months) and almost 70% used analgesics regularly.

The auricular points most commonly detected and used for treatment were *Shen Men*, Posterior Wall in the cervical area, Zero, and C1 (**Fig. 1**). An average of 4 points (4–6) were used per session.

Primary Outcomes

A mean NDI score of 15.6 ± 5.9 at study entry was reduced to 7.9 ± 5.6 at 1 month after treatment ($P < 0.0001$), and 8.8 ± 5.6 at 4 months after treatment ($P < 0.0001$ versus baseline). The VAS score decreased from 4.8 ± 2.4 before treatment to 3.14 ± 2.1 at 1 month after treatment ($P = 0.006$)

TABLE 1. PATIENTS' DEMOGRAPHICS

Variables	Patients (n = 19)
Age	44.5 $\pm$ 15.15
Female	15 (78.9)
Race (white)	16 (84.2)
Right-handed	17 (89.5)
Time (mos)	48 (24–66)
Diabetes mellitus	3 (15.8)
Hypertension	4 (21.1)
Dyslipidemia	4 (21.1)
Smoking	1 (5.3)
Obesity	1 (5.3)
Previous surgery	4 (21.1)
Cervical disease	8 (42.1)
Analgesics	13 (68.4)
Points per session (n)	4 (3–5)

Results are expressed by mean $\pm$ standard deviation, median (quartiles), and n (%).
mos, months.

and 3.21 ± 2.1 at 4 months after treatment ($P = 0.003$). Figures 2 and 3 show the timeline evolution of these scales. No statistical differences were noted between NDI and VAS scores between 1 and 4 months of treatment.

There were 5 patients (25%) in whom the NDI was < 5.0 4 months after treatment, which meant minimal or no disability; and in 10 patients (53%), the VAS for pain was ≤ 2.0 4 months after the last ear acupuncture session. The overall success rates for reducing at least 30% of the initial NDI and VAS scores 4 months after treatment was achieved in 68% of the patients on the NDI, and in 53% on the VAS. No adverse effects associated with the ear acupuncture treatment were reported. Figure 4 provides a summary of the study.

DISCUSSION

This study demonstrated a significant improvement on the NDI and VAS for pain with the use of auriculotherapy. This positive effect remained up to 4 months after treatment discontinuation. These unique and important findings demonstrate that AT can help patients effectively when they have such debilitating problems.

In this study, AT was applied with the French technique. In 2 studies, Alimi et al. investigated the efficacy of AT in patients with pain secondary to cancer.^{9,13} In the first study, 20 patients with insufficiently relieved pain by conventional pharmacotherapy and an average pain index at 7/10 on the VAS were investigated.⁹ The treatment was performed with semipermanent needles (Aiguille Semi-Permanente® [ASP], Sedatelec, Irigny, France) during a single session; 18 of 20 (90%) patients improved with an absolute drop in VAS scores of 3.4 ± 2.2 . In the second study,¹³ 90 patients were randomly assigned into 3 groups of treatment: (1) ASP

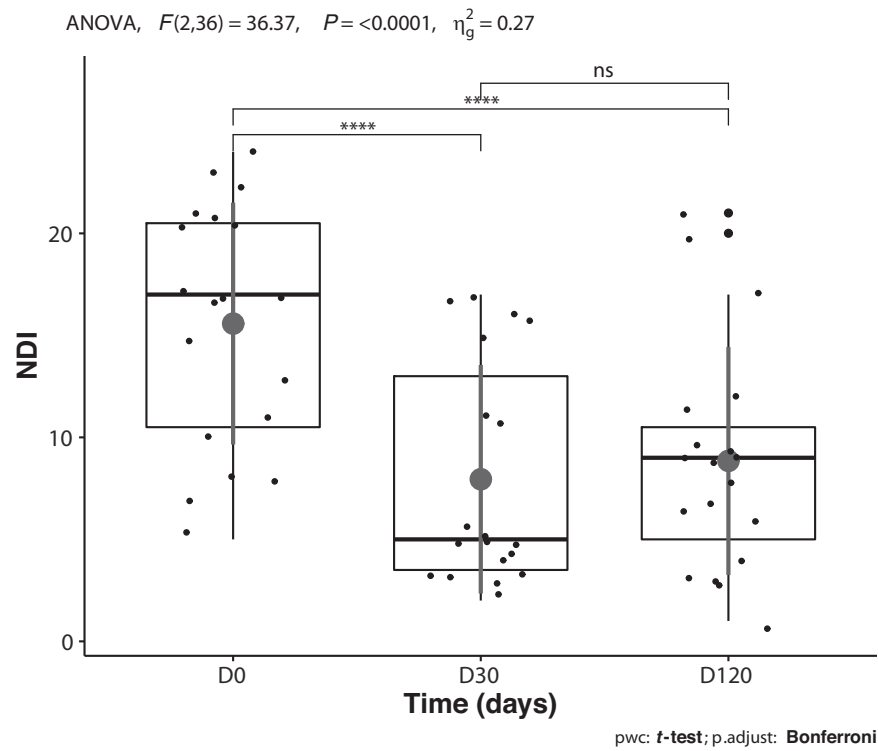


FIG. 2. Neck Disability Index (NDI) before, and at 1 and 4 months after auriculotherapy. Values are shown as median (interquartile range). Grey lines represent mean $\pm$ standard deviation. **** $P \leq 0.0001$ ANOVA, analysis of variance; ns, nonsignificant.

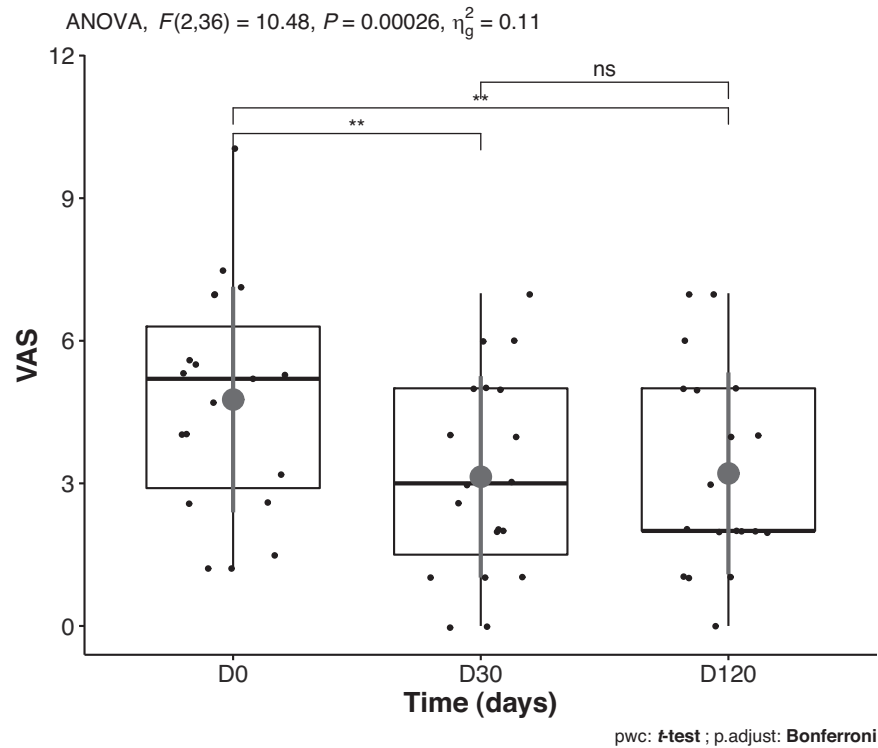


FIG. 3. Visual analogue scale (VAS) for pain before, and at 1 and 4 months after auriculotherapy. Values are shown as median (interquartile range). Grey lines represent mean $\pm$ standard deviation. ** $P \leq 0.01$. ANOVA, analysis of variance; ns, not significant.

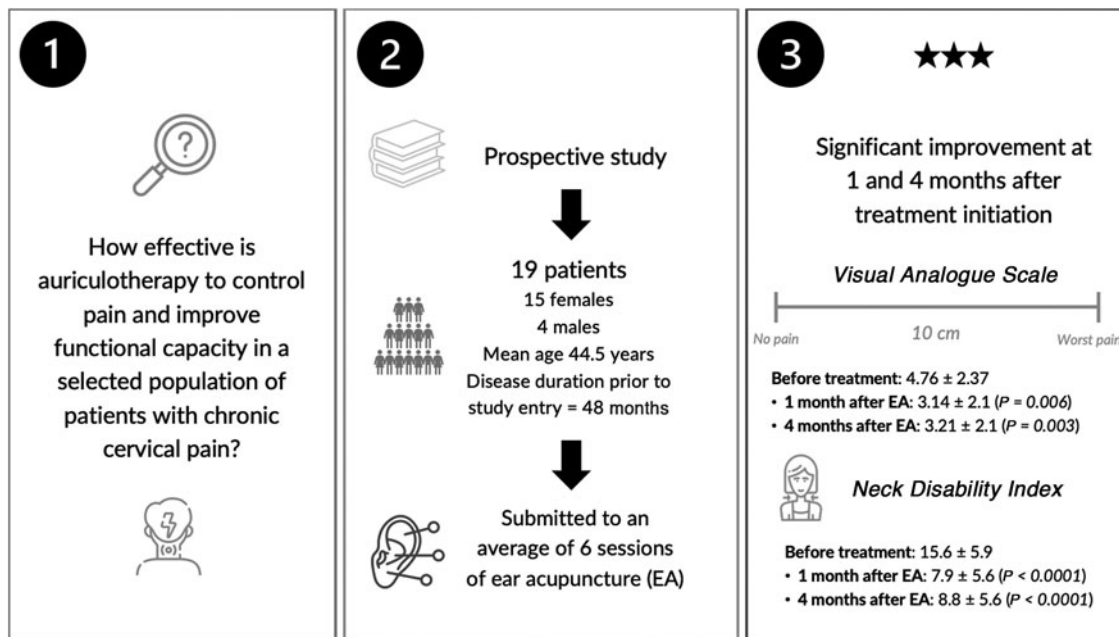


FIG. 4. Summary of the study.

at electrically detected points; (2) needles at undetected points; or (3) seeds at undetected points. Each group of patients received 2 treatment sessions. The average VAS for pain was similar among the groups at study entry and, after 2 months, the VAS score decreased by 36% in the group that had the ASP needles at electrically detected points, and only by 2% in the other 2 groups ($P < 0.0001$). The current study, using the same treatment technique, showed a greater reduction on the pain scale (53%) in patients with chronic cervical pain. Thus, it appears that treating exclusively detected points may lead to better results.

A 2019 randomized trial¹¹ performed AT sessions with seeds in 48 patients with chronic neck pain (25=treatment group and 23=controls) and evaluated the patients NDI and VAS scores for pain 2 weeks later. In the treatment group, a reduction of 38.5% in NDI and 31.4% in the VAS for pain were reported, which were slightly less than the current study's results for the NDI (49% reduction after 1 month and 43% after 4 months) but similar to the reduction noted in the VAS for pain (34% reduction after 1 month and 32.5% after 4 months). This may be related to the fact that our patients were treated with needles and not seeds or had a more severe profile of cervical disability before treatment.

In another study, 21 patients with VAS for cervical pain scores >5 were treated with needles and by using 3 points electrically detected, according to the French cartography.⁷ One group received constant, low-frequency and low-intensity electrical stimulation for 48 hours every week, and the other group was treated with only needles for 48 hours. The treatment was applied for a total of 6 weeks and these patients were reevaluated 3 months after the end of treatment. Pain reduction was significantly greater in the electroacupuncture group;

however, in both groups there was a significant reduction, compared to before treatment, that remained for 3 months. The current study confirmed these findings even at 4 months after treatment discontinuation, raising the hypothesis that the AT duration effect induced by using the French technique, with electrical detection of the points and needles, may confer additional benefit for these patients. The current study did not use auricular electrical stimulation.

In another randomized study published in 2006, Ceccherelli et al.⁸ compared the effect of auricular + systemic acupuncture versus systemic acupuncture for treating myofascial cervical pain. The patients were given 8 sessions over 8 weeks, and were reassessed at 1 and 3 months after the end of treatment. Unlike the current study, the technique used for the 2006 study was Chinese AT, and the points were not detected electrically or by painful palpation. In addition, the group who received AT also received conventional acupuncture. Both groups showed significant reductions in VAS of pain scores at 1 and 3 months after treatment (67% and 65.7%) with no differences between the groups. The more-important reduction in the VAS pain scores in that study may be due to the greater number of sessions and the inclusion criteria that restricted to patients with myofascial cervical pain, in which acupuncture produces good results.¹⁴

The current study had some limitations related to its prospective observational design and small sample size. The follow-up of 4 months after treatment discontinuation, although short for a long-term condition such as chronic neck pain, is the longest follow-up reported for these kinds of studies. The current study adds important data involving the use of AT with the French technique to address chronic neck

pain, as there are very few published studies in this area. Finally, the choice of points was based in reference books from the previous decade,^{1,5} as well-defined protocols are not available.

CONCLUSIONS

This study confirmed the effectiveness of auriculotherapy or ear acupuncture in reducing the scores of pain and neck disability index, in a selected population of patients with cervical pain. The effects lasted for up to 4 months after stopping the treatment. Thus, it reinforced the positive effects of this integrative therapy as well as the need for further investigations in larger randomized trials.

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This trial was registered in the Brazilian Registry of Clinical Trials* (No: RBR-3rkv2pf)

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AUTHORS' CONTRIBUTIONS

Drs. M. Bonacossa Sant'Anna and F. Mendes Sant'Anna designed the study, conducted the research and wrote the article. Dr. L.W. Chao contributed to the revision of the article to add important content. Dr. L. Boncossa Sant'Anna prepared the figures and helped analyze and interpret the data. All of the authors read and approved the final version of the article.

AUTHOR DISCLOSURE STATEMENT

No competing financial conflicts of interest exist.

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